PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Takaaki TERAHARA et al.	Group Art Unit: Not Yet Assigned
U.S. Application No.: 10/525,646	Examiner: Not Yet Assigned
Filed: February 25, 2005	Attorney Docket No.: 7388/84281
Confirmation No.: Not Yet Assigned	Customer No.: 42798

Title: PATCH

SUBMISSION OF INTERNATIONAL PRELIMIANRY EXAMINATION REPORT

Commissioner for Patents
Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22304

Sir:

Applicants submit herewith a copy of the English translation of the International Preliminary Examination Report issued for the basic PCT application (PCT/JP2003/010090) of the above-referenced application.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

Date: **May 10, 2005**

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Translation

PCT/JP2003/010092

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FP03-0198-00	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/010092	International filing date (*day/month/year*) 07 August 2003 (07.08.2003)	Priority date (*day/month/year*) 28 August 2002 (28.08.2002)
International Patent Classification (IPC) or national classification and IPC A61K 47/32, 9/70, 31/405, 31/4422, 31/48, 47/06, 47/12		
Applicant	HISAMITSU PHARMACEUTICAL CO., INC.	

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 04 December 2003 (04.12.2003)	Date of completion of this report 20 May 2004 (20.05.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP2003/010092

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP 03/10092

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-6	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-6	NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims		NO

2. Citations and explanations

Document 1: JP 9-315957 A (Hisamitsu Pharm. Co., Inc.), 09 December 1997

Document 2: EP 993829 A1 (Hisamitsu Pharm. Co., Inc.), 19 April 2000

Document 3: WO 96/40139 A1 (Alza Corp.), 19 December 1996

Document 4: JP 2002-515424 A (Schwarz Pharma AG), 28 May 2002

Document 5: WO 02/38139 A1 (Hisamitsu Pharm. Co., Inc.), 16 May 2002

Document 6: JP 4-368323 A (Sekisui Chemical Co., Ltd.), 21 December 1992

Claims 1, 2, 5 and 6

The invention that is set forth in claims 1, 2, 5 and 6 does not involve an inventive step in the light of documents 1, 2, 5 and 6 cited in the international search report.

Document 1 discloses an apparatus for percutaneous therapy that comprises estradiol and norethisterone acetate as active components, wherein said apparatus is configured from a pressure-sensitive adhesive layer containing a styrene-isoprene-styrene block copolymer, an acrylic acid-2-ethylhexyl/vinyl acetate copolymer and a

saturated cycloaliphatic hydrocarbon resin, which is disposed upon a support (refer to example 1), and document 2 discloses an apparatus for percutaneous therapy that comprises a serotonin receptor antagonizing agent as an active component, wherein said apparatus is configured from a pressure-sensitive adhesive layer containing a styrene-isoprene-styrene block copolymer, an acrylic acid-2-ethylhexyl/vinyl acetate copolymer and a saturated cycloaliphatic hydrocarbon resin, which is disposed upon a support (refer to example 1).

A comparison of the invention that is set forth in claims 1, 2, 5 and 6 and the inventions that are disclosed in documents 1 and 2 shows that a basic nitrogen-containing polymer that comprises basic nitrogen and does not exhibit a self-adhesion property is added to the invention that are is forth in claims 1, 2, 5 and 6, whereas the preparations that are disclosed in documents 1 and 2 do not contain the aforementioned polymer; therefore, these inventions are different.

However, documents 1 and 2 indicate that it is possible to add an absorption promoting agent to the apparatuses for percutaneous therapy (refer to document 1, paragraph [0014] and document 2, paragraph [0013]), and document 5 indicates that the polymers specified in claim 3 improve the percutaneous absorption characteristics of a medicament; therefore, it is not considered to require special creativity for a person skilled in the art to attempt to employ the aforementioned polymers that are disclosed in document 5 as the absorption promoting agent in the invention that is disclosed in document 1. In addition, document 6 indicates that not only the percutaneous absorption characteristics but also the cohesion characteristics of the adhesive agent are improved via the addition of the aforementioned polymers; therefore, it can be said that the effects exhibited by

the invention that is set forth in claims 1, 2, 5 and 6 could have been predicted by a person skilled in the art.

Claims 3 and 4

The invention that is set forth in claims 3 and 4 does not involve an inventive step in the light of documents 1-6 cited in the international search report.

The invention that is set forth in claims 3 and 4 pertains to the medicament in the preparation from the invention that is set forth in claim 1, with claim 3 specifying the level of solubility of the medicament in relation to water and claim 4 specifying medicaments such as pergolide for use in the invention, whereas the medicaments that are specified in claims 3 and 4 are not added to the apparatuses for percutaneous therapy that are disclosed in documents 1 and 2; therefore, these inventions are different.

However, document 1 indicates that it is possible to select a well-known medicament as the active component for the apparatus for percutaneous therapy that is disclosed therein (refer to paragraph [0010]), and the medicaments that are set forth in claims 3 and 4 are well-known medicaments which can be administered percutaneously, as disclosed in documents 3-6; therefore, it would be easy for a person skilled in the art to attempt to employ the dosage form that is disclosed in document 1 or document 2 as the dosage form for the percutaneous administration of pergolide or the like.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 1 is not fully supported by the description.

With regards to the statement "basic nitrogen-containing polymer that comprises basic nitrogen and does not exhibit a self-adhesion property," as set forth in claim 1, even with consideration of the description it is unclear specifically what polymers other than the acrylic polymers such as methyl methacrylate copolymers, butyl methacrylate copolymers and dimethylaminoethyl methacrylate copolymers that are presented as examples in the description are included in the scope of said disclosure, and what polymers are not included in the scope of said disclosure.